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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,919	04/20/2004	Michael J. Adang	UGR-100XD1	6165

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EXAMINER	
LIU, SUE XU	

ART UNIT	PAPER NUMBER
1639	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,919	ADANG ET AL.	
	Examiner	Art Unit	
	Sue Liu	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-37* is/are pending in the application.

4a) Of the above claim(s) *25-34 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-24, 35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/20/04;5/11/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Claims 1-19 have been cancelled.

Claims 20-37 are currently pending.

Claims 25-34 and 37 have been withdrawn.

Claims 20-24, 35 and 36 are being examined in this application.

Election/Restrictions

2. Applicant's election of Group I (claims 20-24, 35 and 36) in the reply filed on 5/11/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election **without** traverse (MPEP § 818.03(a)).

3. Claims 25-34 and 37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected 25-34 and 37, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5/11/07.

4. Upon further consideration, the "Species Election" requirement as set forth in the previous Restriction Requirement (mailed 4/11/07; pp. 4+) is withdrawn. Applicant's election of species is, thus, moot.

Priority

5. This application appears to be a CONTINUATION of U.S. Patent Application Nos. 09/629,596 (filed 7/31/2000), which is now abandoned (4/21/2004). The '596 application claims priority to U.S. Provisional Patent Application Nos. 60/146,646, filed 7/30/1999.

6. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/146,646, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The '646 provisional application fails to provide support for the specific SEQ ID Nos 9 and 10 as recited in the instant claims.

Thus, the effective filing data for the said subject matter is 7/31/2000.

Information Disclosure Statement

7. The IDS filed on 4/20/04 have been considered. See the attached PTO 1449 forms.

8. The information disclosure statement filed 5/11/07 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein regarding R3, R13, and R14 has not been considered. See the attached PTO 1449 form. In addition, the date information for R3 reference is also not provided.

Specification

9. Applicants are also invited to update the continuing data (benefits claimed under 35 USC 119, 120, etc.) in the first line of the specification.

10. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. MPEP 608.01

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written Description Rejection

12. Claims 20-24, 35 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite a phage comprising a polynucleotide molecule that comprises a nucleotide sequence encoding a fusion protein comprising a Cry protein and a phage vector protein, wherein said Cry protein is displayed on the surface of said phage.

The instant claims are drawn to a phage comprising a "polynucleotide molecules". The instant specification does not disclose the specific nucleic acid sequences encoding the fusion proteins of Bt toxin and the phage coat proteins. The specification does not disclose nucleic acid encoding any other fusion proteins of a toxin and a phage coat protein. The specification examples are drawn to the use of specific M13 phage vectors fUSE5 and ASurfZap to prepare the (Bt toxin Cry1Ac and phage coat protein) fusion proteins and display on the surface of the phage. The specification description clearly does not provide adequate representation regarding the open ended product (polynucleotide molecule) of the instant claims.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that "written description of an invention involving a chemical genus, like a description a chemical species, 'requires precise definition, such as structure or formula or chemical name' of an the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1405*

(1997), quoting Fiers v. Revel, 25 USPQ2d 1601, 1601 (Fed. Cir. 1993) [the claims at issue in University of California v. Eli Lilly defined the invention by function of the claimed DNA].

The court holds "An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed.Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606."

"We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein. See , e.g. , In re Deuel , 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1215 (1995) ("A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein."); In re Bell , 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed.Cir. 1993)."

This holding is applicable to the present claimed product or nucleic acid molecule encoding the fusion protein of Bt toxin and phage coat protein because the invention lacks showing of sufficient identifying characteristics or lacks examples of claimed product (polynucleotide molecule encoding the fusion protein) to demonstrate possession of claimed generic.

The examples of the instant disclosure are drawn to fusion proteins of Cry 1Ac (Bt toxin protein) and phage coat proteins and display of the proteins on the phage surface, but no DNA sequences are disclosed. Thus the specification lacks written description support for polynucleotides encoding any toxin and phage coat protein as claimed in the present invention.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(Note: the instant claim numbers are in bold font.)

Marzari

14. Claims 20-22, 24 and 35 are rejected under **35 U.S.C. 102(b)** as being anticipated by Marzari et al (FEBS Letter. Vol. 411: 27-31; 1997; cited in IDS).

The instant claims recite a phage comprising a polynucleotide molecule that comprises a nucleotide sequence encoding a fusion protein comprising a Cry protein and a phage vector protein, wherein said Cry protein is displayed on the surface of said phage.

Marzari et al, throughout the publication, teach using phage to display Cry protein (Abstract). The reference teaches fusing CryIA(a) protein with gene III coat protein of phage through molecular cloning techniques (using plasmid DNA constructs), and displaying the fusion

protein on the surface of the phage particles (e.g. Abstract; p. 27, col.2, para 3; pp. 27-28, bridging paras), which read on the phage of **clm 20**.

The reference teaches the Cry protein is derived from *Bacillus thuringiensis* (e.g. Abstract), which reads on the product by process limitation of **clm 21**.

The reference teaches the g3p coat protein is from filamentous bacteriophages (e.g. p. 27, col.2, para 3), which reads on the product by process limitation of **clms 22 and 24**.

The reference teaches fusing partial CryIA(a) protein with the phage coat protein (e.g. Figure 1; pp. 27-28, bridging), which reads on the "modification" of **clm 35**.

Kasman

15. Claims 20-22, 24, 35 and 36 are rejected under **35 U.S.C. 102(a)** as being anticipated by Kasman et al (Applied and Environmental Microbiology. Vol. 64(8): 2995-3003; 8/1998; cited in IDS).

Kasman et al, throughout the publication, teach using phage to display Cry protein (Abstract). The reference teaches fusing CryIA(c) protein with gene III coat protein of phage through molecular cloning techniques (using plasmid DNA constructs), and displaying the fusion protein on the surface of the phage particles (e.g. Abstract; p.2996, cols1-2, bridging paras), which read on the phage of **clm 20**.

The reference teaches the Cry protein is derived from *Bacillus thuringiensis* (e.g. Abstract), which reads on the product by process limitation of **clm 21**.

The reference teaches the g3p coat protein is from filamentous bacteriophages (e.g. p. 2996, col.1, para 1; Abstract), which reads on the product by process limitation of **clms 22 and 24**.

The reference teaches fusing mutant CryIA(c) protein with the phage coat protein (e.g. p. 2996, col.1; p.2997, col.2, para 3), which reads on the "modification" of **clms 35** and the CrylAc protein of **clm 36**.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Marzari and Others

17. Claims 20-22, 24, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marzari et al (FEBS Letter. Vol. 411: 27-31; 1997; cited in IDS), in view of Stewart et al (Plant Physiology. Vol. 112: 121-129; 1996; cited in IDS), and if necessary, in view of Masson et al (Journal of Biological Chemistry. Vol. 270(35): 20309-20315; 1995; cited in IDS).

Marzari et al, throughout the publication, teach using phage to display Cry protein, as discussed above.

Marzari et al do not explicitly teach the Cry protein is Cry1Ac, as recited in **clm 36**.

However, Stewart et al, throughout the publication, teach Cry1Ac proteins and its encoding polynucleotide (e.g. Abstract; p. 122, col.1, para 4). The reference also teaches the advantages of generating DNA vectors comprising Bt toxins such as increased insecticidal efficiency (e.g. p. 121, col.2, para 3).

In addition, Masson et al, throughout the publication, teach various Cry toxins such as Cry1Ac and Cry1Ab. (Abstract). The Masson reference also teaches the advantages of Cry1Ac toxin such as avoiding insect resistance to the toxin. (e.g. p. 20309, col.2, para 1).

Therefore, it would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to make a phage comprising DNA encoding for the Cry1Ac protein fused to the gIII coat protein of phage.

A person of ordinary skill in the art would have been motivated at the time of the invention to make a phage displaying vector comprising polynucleotides encoding for Cry1Ac protein, because the advantages of using phage displaying technology to study protein mutations as taught by Marzari et al, and the need to generate toxins such as Cry1Ac that would reduce insect resistance, as taught by Masson et al.

A person of ordinary skill in the art would have reasonable expectation of success of achieving such modifications since Marzari et al, Stewart et al, and Masson et al have demonstrated the success of making polynucleotides encoding for Cry toxins, and manipulating phage vectors to encompass Cry toxin encoding DNAs.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SL/
Art Unit 1639
7/19/07

/Jon D. Epperson/
Primary Examiner, AU 1639